



FEDERAL TRADE COMMISSION

[File No. 221 0002]

Hikma Pharmaceuticals PLC/Custopharm, Inc.; Analysis of Agreement Containing Consent Orders to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis of Proposed Consent Orders to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY**

INFORMATION section below. Please write: “Hikma/Custopharm; File No. 221 0002” on your comment and file your comment online at <https://www.regulations.gov> by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Steven Wilensky (202-326-2650), Bureau of Competition, Federal Trade Commission, 400 7th Street SW, Washington, DC 20024.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis of Agreement Containing Consent Orders to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Website at this web address: <https://www.ftc.gov/news-events/commission-actions>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Write “Hikma/Custopharm; File No. 221 0002” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the <https://www.regulations.gov> website.

Due to protective actions in response to the COVID-19 pandemic and the agency’s heightened security screening, postal mail addressed to the Commission will be delayed. We strongly encourage you to submit your comments online through the <https://www.regulations.gov> website.

If you prefer to file your comment on paper, write “Hikma/Custopharm; File No. 221 0002” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website at <https://www.regulations.gov>, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment

should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on <https://www.regulations.gov> – as legally required by FTC Rule 4.9(b) – we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC Website at <https://www.ftc.gov> to read this Notice and the news release describing this matter. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it

receives on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Analysis of Agreement Containing Consent Orders to Aid Public Comment

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Hikma Pharmaceuticals PLC (“Hikma”), Custopharm, Inc. (“Custopharm”), Water Street Healthcare Partners, LLC (“Water Street”), Water Street Healthcare Partners III, L.P. (“Fund III”), Water Street Healthcare Partners IV (“Fund IV”), L.P., and Long Grove Pharmaceuticals, LLC (“Long Grove”) (collectively, “Respondents”). The purpose of the Consent Agreement is to remedy the anticompetitive effects that would likely result from Hikma’s acquisition of Custopharm (“the Proposed Acquisition”). Pursuant to an agreement dated September 27, 2021, Hikma proposes to acquire Custopharm in a transaction valued at approximately \$375 million. As part of the Proposed Acquisition, Custopharm agreed to carve out one of its pipeline products, injectable triamcinolone acetonide (“TCA”), and transferred its TCA assets to Long Grove. The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening future competition in the U.S. market for injectable TCA. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

Under the terms of the proposed Decision and Order (“Order”), Respondent Hikma shall not acquire any rights or interests in TCA products or assets, or any rights or interests in the therapeutic equivalent or biosimilar of TCA products without the prior

approval of the Commission. The Order requires Respondents Long Grove and Water Street to operate and maintain in the normal course of business the TCA assets previously operated by Custopharm for a period lasting until four years after the Order date.

The consent agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the consent agreement, modify it, or make final the proposed Order.

I. The Respondents

Respondent Hikma is a multinational pharmaceutical company with headquarters in London, England, and U.S. headquarters in Berkeley Heights, New Jersey. Hikma manufactures both branded and generic pharmaceutical products, including generic injectables.

Respondent Custopharm is incorporated in the State of Texas with its principal place of business located in Carlsbad, California. Water Street owns a majority of Custopharm. Custopharm develops generic pharmaceutical products but does not have any of its own manufacturing capabilities and manufactures its products exclusively through contract manufacturers. Those products are then sold through Custopharm's commercial arm, Leucadia Pharmaceuticals.

Respondent Water Street Healthcare Partners, LLC is a private equity firm headquartered in Chicago, Illinois. Water Street is the General Partner of Respondents Fund III and Fund IV. Respondent Fund III is a private equity fund managed by Water Street located in Chicago, Illinois. Fund III's portfolio includes Custopharm. Respondent Fund IV is a private equity fund managed by Water Street located in Chicago, Illinois. Fund IV's portfolio includes Long Grove. Respondent Long Grove is a pharmaceutical

company launched in 2019 and headquartered in Rosemont, Illinois. Long Grove is owned by Fund IV.

II. The Relevant Market

In human pharmaceutical markets, prices generally decrease as the number of generic competitors increases. Prices continue to decrease incrementally with the entry of the second, third, fourth, and further pharmaceutical competitors. Accordingly, a reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Acquisition would reduce future competition in the market for injectable TCA. Injectable TCA is a corticosteroid used for severe skin conditions and inflammation. Only three competitors currently market injectable TCA: Bristol-Meyers Squibb, Amneal Biosciences, and Teva Pharmaceutical Industries. Hikma and Custopharm are two of a limited number of suppliers capable of entering the TCA market in the near future.

III. Entry

Entry into the market at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

IV. Competitive Effects

The effect of the Proposed Acquisition, if consummated, is likely to substantially lessen competition by eliminating future competition between Hikma and Custopharm in the market for injectable TCA. The evidence shows that the Proposed Acquisition, absent a remedy, would eliminate an additional independent entrant in the currently concentrated market for injectable TCA, which would have enabled customers to negotiate lower prices. Customers and competitors have observed—and the pricing data confirms—that

the price of pharmaceutical products decreases with new entry even after several other suppliers have entered the market. Thus, absent a remedy, the Proposed Acquisition likely would cause U.S. consumers to pay significantly higher prices for injectable TCA in the future.

V. The Proposed Order

The proposed Order effectively remedies the competitive concerns raised by the Proposed Acquisition for the pharmaceutical product at issue. The proposed Order requires that Hikma not acquire any rights or interests in TCA products or assets, or rights or interests in the therapeutical equivalent or biosimilar of TCA products without the prior approval of the Commission. The proposed Order also requires Water Street and Long Grove to operate and maintain in the normal course of business the TCA assets for a period lasting until four years after the date the Order is issued. The proposed Order also allows the Commission to appoint an individual to serve as Monitor to observe and report on Respondents' compliance with their obligations set forth in the Order.

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The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the proposed Order and does not modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Secretary.

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